AUG 28 1996

510 (k) SUMMARY

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Bio-Plexus, Inc. 384 Merrow Road Tolland, CT 06084

CONTACT: Carl R. Sahi (President)

Prepared:

March 6, 1996

Revised:

July 9, 1996

Proprietary Name:

BIO-PLEXUSTM Needle Disposal Container

Generic Name:

Sharps Container

Classification Name:

Accessory to Blood Collection Needles, Winged

Sets and Catheters of Appropriate Size

Class:

H

Panel Code: Product Code: 80 FMI

Reason for submission:

new device

Bio-Plexus Inc. Registration Number:

1224632

The BIO-PLEXUSTM Needle Disposal Container is a single use, one quart, puncture resistant container comprised of a bucket like base and an affixed cover. The bucket and the cover are plastic injection molded from polypropelene. The cover has three openings and two hinged lids. The BIO-PLEXUSTM Needle Disposal Container performs the same function as other legally marketed sharps containers, for example, the Vacutainer[®] Needle Disposal Container 367201. Specifically, this is to receive and accumulate contaminated blood collection needles and accessories in a puncture resistant container until final disposal can occur. The BIO-PLEXUSTM Needle Disposal Container is to be used by healthcare workers in healthcare facilities and in the home healthcare setting for the disposal of contaminated **PUNCTUR-GUARD**[®] needles and accessories.